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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/740,206 | 12/17/2003 | Anne Marie Vitrant | 454.005 | 2133 |

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EXAMINER

REYES, HECTOR M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/740,206 | Applicant(s) VITRANT ET AL. | |
| | Examiner Hector M Reyes | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 1, 14, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 2-13 and 15-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/17/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of The Claims

Claims 1-22 have been amended via preliminary amendment and are currently under Examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 14, 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, n has been defined as 1, 2 or 3. The said variable number defines the number of times that the variable moiety R1 is present in the phenyl ring of the benzylic alcohol. R1 embraces hydrogen by definition. Therefore, in those instances wherein R1 is hydrogen, and the maximum amount of hydrogen atoms, as defined by n is 3, it is unclear what other two substituents are present in the said ring. Clarification is requested.

Claim 14 recites the limitation "the process of claim 1 wherein the solvent/water azeotrope is distilled off..." There is insufficient antecedent basis for this limitation in the claim because claim 1 does not have the limitation of a solvent/water azeotrope.

Claim 18 is ambiguous and unclear: the phrase "the process of claim 1 wherein a solvent for the alcohol derivative is added to the medium comprising the ester to be

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released". Why the alcohol requires a solvent? From where is the said ester liberated?

Is the said solvent added to the reaction mixture?

In claims 20-21 are ambiguous since the claimed compounds lack definition. For instance it is unclear what compounds are or not embraced in the definition used to characterize the compound. What is the structure of the claimed derivatives? Similarly in claim 21, while the position of the moiety A is properly defined it is unclear what chemical moieties would satisfy the limitations of the said claim. If A is a part of a molecule, can A be hydrogen? Nitro? Nitrogen? Phosphorus? Clarification is requested.

Claims Objected

Claims 2-13 and 15-19 are hereby objected because of its dependency from rejected claim 1.

Allowable Subject Matter

The process outlined in the instant claims or the compounds claimed in claim 22 were not found disclose in the prior art. The closest art was found in:

- Rapoport et al, J. Org. Chem., 55, pp3068-3074 and
- Clayton et al, Peptides, Journal Chemical Society, 1956, pp371-380.

Rapoport discloses the synthesis of Vincamine from aspartic acid. As part of the synthesis, the preparation of the corresponding monoester of aspartate 14 is disclosed via the specific hydrolysis of the corresponding diester using copper (II).

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On the other hand, benzyl hydrogen l-glutamic acid ester is disclosed by Clayton via the reaction of benzyl alcohol and glutamic acid using p-toluene sulfonic acid. Clayton however does not disclose the use of an alkane sulfonic acid as required in the instant invention. Clayton yield of 43 % does not suggests that using alkane sulfonic acid in place of p-toluene sulfonic acid would increase the reaction yield and product purity as claimed in the instant invention.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hector M. Reyes, whose telephone number is (571) 272-0691. The Examiner can normally be reached Monday through Friday from 9:30 to 5:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner 's supervisor Ms. Cecilia Tsang can be reached at (571) 272-0562 or the Examiner's primary Ms. Rita Desai, at 571-272-0684

Hector M. Reyes, PhD JD
Reg # P-54,846
AU 1625
September 28, 2004

RDesai
9/28/04